REMARKS

In the Office Action dated August 3, 2000, the Examiner has set forth a requirement for restriction under 35 U.S.C. §121 as follows:

I. Claims 1-19, and 26-32 drawn to polyclonal antisera, transgenic non-human animals, antisera produced by such transgenic animals, and methods of producing such transgenic animals, classified in class 530, 530, 800, and 800 subclass 389.1, 389.4, 14, and 24.

II. Claims 20-25, drawn to methods of neutralizing an antigen in a human, classified in class 424, subclass 133.1

In support of the present restriction requirement, the Examiner has alleged that Group I and Group II are unrelated. The Examiner states that inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP §806.04, MPEP §808.01). The Examiner contends that Group I and Group II have different functions, since the antisera of Group I can be used to detect an antigen in a Western blot assay, and the methods of Group II can be used to treat a disease in humans. Thus, the Examiner concludes that Group I and Group II are distinct. The Examiner also alleges that Group I and Group II have acquired a separate status in the art because of their recognized divergent subject matter and separate search requirement. Thus, the Examiner concludes that restriction for examination purposes is proper.

In order to be fully responsive to the Examiner's requirement for restriction, Applicants provisionally elect to prosecute the subject matter of Group I, Claims 1-19 and 26-32, drawn to polyclonal antisera, transgenic non-human animals, antisera produced by such transgenic animals, and methods of producing such transgenic animals. Applicants reserve the right to file one or more divisional applications directed to the non-elected subject matter in this application.

However, pursuant to 37 C.F.R. §§ 1.111 and 1.143, Applicants hereby traverse the Examiner's requirement for restriction and request reconsideration thereof in view of the following remarks.

An Examiner's authority to require restriction is defined and limited by statute:

> If two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions.

35 U.S.C. § 121, first sentence (emphasis added). The implementing regulations of the Patent and Trademark Office include the mandate that restriction is appropriate only in cases presenting inventions which are both independent and distinct, 37 C.F.R. §§1.141-142. Without a showing of independence and distinctness, a restriction requirement is unauthorized.

In the present application, the claims which the Examiner has grouped separately are not "independent and distinct" so as to justify the restriction requirement. Specifically, Applicants submit that the methods of Group II, i.e., methods of neutralizing an antigen in a human require the use of the polyclonal antisera of Group I. Clearly Group II is related to and not independent of Group II.

Furthermore, Group I includes claims drawn to polyclonal antisera, transgenic animals which are used in producing such antisera, the methods of making the transgenic animals, as well as the methods of making the antisera. Applicants respectfully submit that Group II is merely another aspect of the present invention, i.e., the use of the polyclonal antisera. The courts have recognized that it is in the public interest to permit Applicants to claim several aspects of their invention together in one application, as the Applicants have done herein. The CCPA has observed:

> We believe the constitutional purpose of the patent system is promoted by encouraging Applicants to claim, and therefore to describe in the manner required by 35 U.S.C. §112 all aspects as to what they regard as their invention, regardless of the number of statutory classes involved.

In re Kuehl, 456 F.2d 658, 666, 117 U.S.P.Q. 250, 256 (CCPA 1973). This interest is consistent with the practical reality that a sufficiently detailed disclosure supporting claims to one aspect of an invention customarily is sufficient to support claims in the same application to other aspects of the invention.

Applicants respectfully suggest that in view of the continued increase of official fees and the potential limitation of an applicant's financial resources, a practice which arbitrarily imposes restriction requirements may become prohibitive and thereby contravene the constitutional purpose to promote and encourage the progress of science and the useful arts. Moreover, under the regulatory changes as a consequence of the General Agreement on Trade and Tariffs (GATT), Applicants are required to conduct simultaneous prosecution, as here, requiring excessive filing costs or to otherwise compromise the term of related patent assets.

It is vital to all Applicants that restriction requirements issue only with the proper statutory authorization, because patents issuing on divisional applications which are filed to prosecute claims that the Examiner held to be independent and distinct can be vulnerable to legal challenges alleging double patenting. The third sentence of 35 U.S.C. § 121, which states that a patent issuing on a parent application "shall not be used as a reference" against a divisional application or a patent issued thereon, does not provide comfort to Applicants against such allegations. The Court of Appeals for the Federal Circuit has declined to hold that § 121 protects a patentee from an allegation of same-invention double patenting, Studiengesellschaft Kohle GmbH v. Northern Petrochemical Co., 784 F.2d 351, 355, 288 U.S.P.Q. 837, 840 (Fed. Cir. 1986). In Gerber Garment Technology Inc. v. Lectra Systems Inc., 916 F.2d 683, 16 U.S.P.Q. 2d 1436 (Fed. Cir. 1990) the court held that § 121 does not insulate a patentee from an allegation of "obviousness-type" double patenting, and in fact affirmed the invalidation on double patenting grounds of a patent that had issued from a divisional application filed following a restriction requirement. Furthermore, it is far from clear that the step of filing a terminal

disclaimer is available to resolve a double patenting issue that arises after the issuance of a patent on the divisional application.

All these considerations indicate that the imposition of a restriction requirement with inadequate authority can lead to situations in which an applicant's legitimate patent rights are exposed to uncertainty and even extinguished. Accordingly, to protect a patentee's rights and to serve the public interest in the legitimacy of issued patents, Applicants respectfully urge the Examiner not to require restriction in cases such as the present application wherein various aspects in a unitary invention are claimed.

In view of the foregoing comments, it is respectfully urged that the Examiner reconsider and withdraw the requirement for restriction and provide an action on the merits with respect to all the claims.

Respectfully submitted,

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